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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,920	09/30/2003	Christopher P. Knapp	279.640US1	2079

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH
1600 TCF TOWER
121 SOUTH EIGHT STREET
MINNEAPOLIS, MN 55402

EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,920	KNAPP ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-29-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on 29 March 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the USP Document Number listed as US-4,711,251 B1 does not correspond to the publication, name of Patentee or Applicant of cited Document or Filling Date with which it is listed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "helix 100" (page 4, line 5). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the applicant will

be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 11, 40 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the matrix". There is insufficient antecedent basis for this limitation in the claim.

Claim 40 recites the limitation "the matrix". There is insufficient antecedent basis for this limitation in the claim.

Claim 44 recites the limitation "the helix". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3–4, 6, 12–14, 16, 18–20, 30, and 33–34 are rejected under 35 U.S.C. 102(b) as being anticipated by Stokes, U.S. Patent 4,506,680.

Stokes discloses an electrical lead comprising a lead body and an electrical conductor (Figs. 1–3); and an electrode coupled to an electrical conductor (Figs. 2–3), wherein an electrode includes a coating on at least a portion of a surface of an electrode (Figs. 2–3), a coating including two or more layers, with a first layer adjacent a surface of an electrode including an insulative material and a second layer adjacent a first layer including at least one pharmacological agent (Figs. 2–3; column 3, lines 50– 51; column 1, lines 65– 68) (claim 1); an electrical pulse generator (column 4, line 27); an electrical lead releasably coupled to electrical pulse generator (column 2, lines 32–33), wherein an electrical lead includes a lead body and an electrical conductor (Figs. 1–3); and an electrode coupled to an electrical conductor (Figs. 2–3), wherein an outer surface of an electrode is coated with two or more layers comprising an insulative material (Figs. 2–3) and at least one pharmacological agent (column 3, lines 50– 51; column 1, lines 65– 68) (claim 16); an electrical lead comprising a lead body and an electrical conductor; and an electrode coupled to the electrical conductor, wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including two or more layers, with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of a pharmacological agent (column 3, lines 13–16) and an outer layer including only a pharmaceutical agent such that a pharmaceutical agent of an outer layer is exposed to tissue upon implant of an electrode (column 3, lines 50– 55) (claim 30).

Stokes discloses a pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof (claims 3, 6, 13, 18, 33, 34) (column 1, lines 65–68); an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt

thereof (claims 4, 7, 14, 19) and an anti-inflammatory agent is dexamethasone (claim 20) (column 2, lines 1–2); an outer layer, wherein an outer layer includes at least one pharmacological agent (claim 12) (column 4, lines 50–54).

7. Claims 35–36 and 41–42 are rejected under 35 U.S.C. 102(b) as being anticipated by Vachon et al., U.S. Patent 5,324,324.

Vachon discloses coating an electrode with a first layer (Fig. 2), wherein a first layer comprises a polymeric base coat (column 3, lines 31–33); and coating an electrode with a second layer, wherein a second layer comprises a polymer and at least one pharmacological agent, and at least partially coats a first layer (Fig. 2; column 5, lines 34–41 and 62–64); a pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof (column 4, lines 30–32); an outer layer, wherein an outer layer comprises at least one pharmacological agent (column 5, lines 62–64).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes as applied to claim 1 above, and in view of Vachon et al., U.S. Patent 5,324,324.

Stokes discloses a first layer comprises a polymeric base coat on an electrode surface and a second layer at least partially covers a polymeric base coat (Figs. 2–3). Stokes does not disclose a second layer comprises a matrix including a polymer and at least one pharmacological agent (claim 5). However, Vachon discloses a second layer comprises a matrix including a polymer and at least one pharmacological agent (Fig. 2; column 5, lines 34–41 and 62–64) to suppress or reduce the inflammatory response and growth of the fibrous capsule.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include a second layer comprises a matrix including a polymer and at least one pharmacological agent, as taught by Vachon to suppress or reduce the inflammatory response and growth of the fibrous capsule.

With respect to claim 8, Stokes discloses the claimed invention except for a coat is ethylene vinyl alcohol. It would have been an obvious to a person of ordinary skill in the art at the time the invention was made to modify the polymeric base coat as taught by Stokes, to be ethylene vinyl alcohol, since it is well known in the art that hydrophilic polymers are easily absorbed by the body with no adverse effects and, advantageously, can deliver therapeutic agents effectively.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include ethylene vinyl alcohol to effectively facilitate delivery of therapeutic agents.

11. Claims 9–10, 15, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes as applied to claims 1 and 30 above, and in view of MacGregor, U.S. Patent 4,281,669.

Stokes does not disclose a third layer above a second layer, wherein a third layer includes a porous barrier (claim 9) and a porous barrier comprises a polymeric coating (claim 10) and a first layer is adapted to functionally increase an impedance of the electrode (claim 15) and a third layer directly adjacent a surface of an electrode comprising a polymer primer layer, with an inner layer adjacent a polymer primer layer (claim 32). However, MacGregor discloses a third layer includes a porous barrier and a porous barrier comprises a polymeric coating and a first layer is adapted to functionally increase an impedance of the electrode and a third layer directly adjacent a surface of an electrode comprising a polymer primer layer, with an inner layer adjacent a polymer primer layer (Fig. 2) to promote the formation of a smooth thin adherent tissue coating on the porous surface rendering the same resistant to the formation of blood clots normally associated with the presence of foreign bodies in the blood stream (column 1, lines 51–56) and to provide excellent wear and strength characteristics in the cardiovascular implant or device (column 3, lines 48–51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include a third layer above a second layer, wherein a third layer includes a porous barrier and a porous barrier comprises a polymeric

coating and a third layer directly adjacent a surface of an electrode comprising a polymer primer layer, with an inner layer adjacent a polymer primer layer, as taught by MacGregor to enhance the electrode's function when implanted.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes and MacGregor as applied to claim 9 above, and further in view of Vachon et al., U.S. Patent 5,324,324.

MacGregor discloses a third layer (Fig. 2), but neither MacGregor nor Stokes discloses that it regulates the release of a pharmacological agent from a matrix. However, Vachon discloses that a layer regulates the release of a pharmacological agent from a matrix (column 5, lines 34–41, 62–64, 12–14 and 29–33; column 6, lines 26–29) to ensure optimum dispensing of the pharmacological agent to the desired treatment site.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Stokes and MacGregor to include a layer regulates the release of a pharmacological agent from a matrix, as taught by Vachon to ensure optimal treatment of the affected site.

13. Claims 38–40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon et al. as applied to claim 35 above, and in view of MacGregor, U.S. Patent 4,281,669.

With respect to claim 38, Vachon discloses the claimed invention except for a coat is ethylene vinyl alcohol. It would have been an obvious to a person of ordinary skill in the art at the time the invention was made to modify the polymeric base coat as taught by Stokes, to be

ethylene vinyl alcohol, since it is well known in the art that hydrophilic polymers are easily absorbed by the body with no adverse effects and, advantageously, can deliver therapeutic agents effectively.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include ethylene vinyl alcohol to effectively facilitate delivery of therapeutic agents.

Vachon et al. discloses a layer regulates the release of the pharmacological agent from a matrix (column 5, lines 34–41, 62–64, 12–14 and 29–33; column 6, lines 26–29), but does not disclose a third layer, wherein a third layer comprises a porous barrier. However, MacGregor discloses a third layer, wherein a third layer comprises a porous barrier (Fig. 2) to promote the formation of a smooth thin adherent tissue coating on the porous surface rendering the same resistant to the formation of blood clots normally associated with the presence of foreign bodies in the blood stream (column 1, lines 51–56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include a third layer, wherein a third layer comprises a porous barrier, as taught by MacGregor to enhance the electrode's function when implanted.

14. Claims 37 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon et al. as applied to claims 36 and 42 above, and in view of Stokes, U.S. Patent 4,506,680.

Vachon does not disclose an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof. However, Stokes discloses an

anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof (column 2, lines 1–2) to render a chronic reduction of pacing and sensing thresholds (column 2, lines 4–5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof. However, Stokes discloses an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof, as taught by Stokes to render a chronic reduction of pacing and sensing thresholds.

15. Claims 21–24 and 28–29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes U.S. Patent 4,506,680.

Regarding claim 21, Stokes discloses the claimed invention except for two or more layers comprise a first layer and a second layer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include two or more layers comprise a first layer and a second layer, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Stokes discloses a pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof (claims 22 and 28) (column 1, lines 65–68); an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof (claims 23 and 29) (column 2, lines 1–2).

With respect to claim 24, Stokes discloses the claimed invention except for a coat is ethylene vinyl alcohol. It would have been an obvious to a person of ordinary skill in the art at the time the invention was made to modify the polymeric base coat as taught by Stokes, to be ethylene vinyl alcohol, since it is well known in the art that hydrophilic polymers are easily absorbed by the body with no adverse effects and, advantageously, can deliver therapeutic agents effectively.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include ethylene vinyl alcohol to effectively facilitate delivery of therapeutic agents.

16. Claims 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes as applied to claim 21 above, and further in view of MacGregor, U.S. Patent 4,281,669.

Stokes does not disclose a third layer, wherein a third layer comprises a porous barrier. However, MacGregor discloses a third layer, wherein a third layer comprises a porous barrier (Fig. 2) to promote the formation of a smooth thin adherent tissue coating on the porous surface rendering the same resistant to the formation of blood clots normally associated with the presence of foreign bodies in the blood stream (column 1, lines 51–56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified invention of Stokes to include a third layer comprises a porous barrier, as taught by MacGregor to enhance the electrode's function when implanted.

With respect to claim 27, Stokes discloses the claimed invention except for a fourth layer. It would have been obvious to one of ordinary skill in the art at the time the invention was made

to include a fourth layer, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

17. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes and MacGregor as applied to claim 25 above, and further in view of Vachon et al., U.S. Patent 5,324,324.

MacGregor discloses a third layer (Fig. 2), but neither MacGregor nor Stokes discloses that it regulates the release of a pharmacological agent from a matrix. However, Vachon discloses that a layer regulates the release of a pharmacological agent from a matrix (column 5, lines 34–41, 62–64, 12–14 and 29–33; column 6, lines 26–29) to ensure optimum dispensing of the pharmacological agent to the desired treatment site.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Stokes and MacGregor to include a layer regulates the release of a pharmacological agent from a matrix, as taught by Vachon to ensure optimal treatment of the affected site.

18. Claims 2, 17, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes as applied to claims 1, 16 and 30 above, and in view of Berthelsen, U.S. Patent 4,953,564.

Stokes does not disclose an electrode includes a helical tip/helix. However, Berthelsen discloses an electrode includes a helical tip/helix (Figs. 1–3) to assist in delivering a drug from a

controlled release device and limiting it to the immediate vicinity of the distal end of the lead, rather than allowing the drug to be dispersed into the blood stream (column 1, lines 62–66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified invention of Stokes to include an electrode includes a helical tip/helix, as taught by Berthelsen to assist in controlled delivery of a drug.

19. Claims 44–45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon et al. as applied to claim 35 above, and in view of Berthelsen, U.S. Patent 4,953,564.

Vachon discloses a coating is applied by contacting an exterior and a composition comprising at least one polymer and at least one pharmacological agent (Figs. 2–3; column 5, lines 34–41 and 62–64), but not an exterior of a helix. However, Berthelsen discloses a helix (Figs. 1–3) to assist in delivering a drug from a controlled release device and limiting it to the immediate vicinity of the distal end of the lead, rather than allowing the drug to be dispersed into the blood stream (column 1, lines 62–66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified invention of Vachon to include a helix, as taught by Berthelsen to assist in controlled delivery of a drug.

Vachon discloses contacting includes spraying (column 4, lines 46–48).

Conclusion

20. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
January 21, 2006

21 January 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/21/6